

Remarks/Arguments:

I. Status

The Office Action dated November 18, 2004, has been carefully reviewed. Claims 1-31 are pending in this application. Claims 1-29 have been rejected. Claims 30 and 31 are newly presented. Claims 1, 9, 18 and 22 have been amended to more particularly recite limitations inherent in the claim as originally filed. Claim 17 has been amended to avoid antecedent basis problems. Reconsideration of this application is respectfully requested.

Claims 1-5, 7, 9-13, 15, 17-20, 22-26 and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kennedy, U.S. Patent No. 5,360,446 (hereinafter "Kennedy"). Claims 6, 14 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kennedy in view of Gibbs, U.S. Patent Publication 2003/0212459 (hereinafter "Gibbs"). Claims 8, 16, 21 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kennedy in view of Digioia, III et al., U.S. Patent No. 205,411 (hereinafter "Digioia et al.").

II. 35 U.S.C. § 102 Rejection.

Claims 1-5, 7, 9-13, 15, 17-20, 22-26 and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kennedy. An anticipation rejection under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element and limitation of the claim. Reconsideration of these claims in view of the following remarks is respectfully requested.

The Present Invention

The present invention as claimed is for a prosthesis for a joint socket, in particular in some claims an acetabular component of a hip prosthesis, and methods of making the same comprising the steps of acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient, computing a second set of data based upon the first set of data and manufacturing the prosthesis to include a functional part and an attachment part extending therefrom. At least the attachment part is manufactured based on the second set of data. Thus the present invention relates to the component of a prosthesis that replaces the socket of a ball and socket joint.

Kennedy

Kennedy discloses an interactive prosthesis design system that uses two x-rays taken from different perspectives to generate data from which a prosthesis component is manufactured. The component manufactured using the generated data in Kennedy is the stem of a femoral component of a hip prosthesis. The stem is configured based on data derived from the x-rays to fit appropriately in the medullary canal of the femur. Kennedy does not indicate that the method disclosed therein is to be utilized to manufacture the acetabular cup against which a head portion of the femoral component bears. Thus, the prosthesis manufactured in Kennedy is not a socket joint prosthesis nor is it an acetabular prosthesis.

Discussion Re: Patentability of Claims 1, 9, 18 and 22

1. Independent Claim Recitations

Claim 1 as amended recites:

1. A method of making an **acetabular prosthesis** comprising the steps of:
 - acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient;
 - computing a second set of data based upon the first set of data; and
 - manufacturing said prosthesis to include an acetabular cup and an attachment part extending therefrom **configured to attach the acetabular cup to bone surrounding the acetabulum of a patient**,
wherein said manufacturing step includes the step of forming said attachment part based on the second set of data.

Claim 9 as amended recites:

9. A method of making a **prosthesis for a joint socket** comprising the steps of:
 - acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient;
 - computing a second set of data based upon the first set of data; and
 - manufacturing said prosthesis to include a functional part and an attachment part extending therefrom **configured to attach the functional part to the bone surrounding the joint socket**,
wherein said manufacturing step includes the step of forming said attachment part based on the second set of data.

Claim 18 recites:

18. A method of making an **acetabular prosthesis** comprising the steps of:
 - acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient;
 - computing a second set of data based upon the first set of data;
 - manufacturing said prosthesis to include an acetabular cup and an attachment part extending therefrom **configured to attach the acetabular cup to bone surrounding the acetabulum of a patient**, wherein said manufacturing step includes the steps of:
 - forming said attachment part based on the second set of data,
 - forming said attachment part to include a bone-facing surface and a tissue-facing surface, and

forming said tissue-facing surface to be a partial facsimile of a surface of said bone.

Claim 22 as amended recites:

22. An **acetabular prosthesis**, comprising:
an acetabular cup; and
a flange attached to said acetabular cup and **configured to attach the acetabular cup to bone surrounding the acetabulum of a patient**, said flange is prepared by a process including the steps of:
acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient;
computing a second set of data based upon the first set of data; and
manufacturing said flange based upon the second set of data.

Claims 1, 9, 18 and 22, as amended all recite in one fashion or another that the prosthetic component manufactured utilizing three dimensional data be the component for attachment to the bone in which the socket component of a joint is located. The hip joint is a ball and socket joint in which the socket component of the joint is in the acetabulum and the ball component is in the femur. In a total hip replacement a femoral (ball component) prosthesis and an acetabular (socket component) prosthesis cooperate to form an artificial ball and socket joint.

The preambles of the independent claims as originally filed all recited that the prosthesis being manufactured or claimed was either an "acetabular prosthesis" (claims 1, 18 and 22) or a "prosthesis for a joint socket" (claim 9). Thus, the independent claims as originally filed envisioned that the prosthesis claimed or being manufactured would cooperate with either a bone forming a ball of a ball and socket joint or a prosthesis replacing a portion of a

bone forming part of a ball and socket joint, e.g. a femoral prosthesis. The independent method claims as originally filed required that the claimed prosthesis be manufacture to include an acetabular cup (or a functional part) and an attachment part extending therefrom. The independent device claim recited an acetabular prosthesis comprising an acetabular cup and a flange attached to said acetabular cup. Thus, all of the claims envisioned that the attachment part or flange be a part of the acetabular or socket joint prosthesis and not a component of the prosthesis with which the acetabular or socket joint prosthesis cooperates to form a total hip or ball and socket joint replacement prosthesis. The examiner apparently disregarded this limitation and reasoned that the stem component of the femoral prosthesis of Kennedy (which is formed using data relating to the femur) "extends" from or is "attached to" the acetabular cup or functional part of the prosthesis and thus satisfied the limitations of the independent claims. This reasoning was flawed. The stem of the femoral prosthesis in Kennedy is a part of a separate prosthesis and cannot serve to satisfy the limitations of the independent claims as originally filed.

The amendments to the independent claims more particularly recite the above limitations of the independent claims as originally filed and thus is not believed to be narrowing. It is believed that Kennedy cannot meet the limitations of the independent claims either as originally filed or as amended and thus does not anticipate claims 1, 9, 18 or 22.

Discussion Re: Patentability of Claims 2-5, 7, 10-13, 15, 17, 19-20, 23-26 and

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Claims 2-5 and 7 depend directly or indirectly from claim 1, claims 10-13, 15 and 17 depend directly or indirectly from independent claim 9, claims 19-20 depend directly or indirectly from independent claim 18 and claims 23-26 and 28 depend directly or indirectly from independent claim 22. Since Kennedy fails to disclose all of the elements or limitations of the independent claims, Kennedy cannot disclose all of the elements or limitations of the dependent claims. Thus, for at least the reasons discussed above relating to the patentability of claims 1, 9, 18 and 22, Kennedy does not anticipate claims 2-5, 7, 10-13, 15, 17, 19-20, 23-26 and 28.

III. 35 U.S.C. § 103 Rejection as being Unpatentable over Kennedy in

View of Gibbs

Claims 6, 14 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kennedy in view of Gibbs. Reconsideration of these claims in view of the following remarks is respectfully requested.

Gibbs

Gibbs discloses a trial system for an acetabular prosthesis with an acetabular cup having a plurality of flanges extending therefrom and a plurality of augment or spacer members for disposing between the flanges and the bone surrounding the acetabulum of a patient. A trial shell is provided for insertion into the acetabular cup for trialing a range of motion of the hip joint before

implanting a prosthetic shell into the acetabular prosthesis. Gibbs does not disclose that the flanges of the acetabular prosthesis are designed utilizing a second set of data derived from a first set of three dimensional data as required by each independent claim of applicant's application. In fact, the augment or spacer members are provided to compensate for the fact that the attachment members are not formed to coincide with the shape of the bone to which the prosthesis is to be attached. Gibbs, pars. 0063-0064.

Discussion Re: Patentability of Claims 6, 14 and 27

Claims 6, 14 and 27 were rejected under 35 U.S.C. § 103 as being unpatentable over Kennedy in view of Gibbs. Reconsideration of these claims in view of the following remarks is respectfully requested.

MPEP § 2143.03 accurately states the law that if an independent claim is non-obvious, then any claim depending therefrom is non-obvious. Claim 6 depends from independent claim 1. Claim 14 depends through dependent claims 13 and 12 from independent claim 9. Claim 27 depends directly from independent claim 22.

Independent claims 1, 9, 18 and 22 recite limitations that are not present in Kennedy as discussed above. Kennedy fails to disclose a prosthesis (either acetabular or for a socket joint) that includes a functional part or acetabular cup and an attachment part. Gibbs discloses an acetabular prosthesis that includes an acetabular cup (functional part) and an attachment part. However, the attachment part of the Gibbs prosthesis is not manufactured using a second set of data derived from a first set of three dimensional data regarding the bone to which

the prosthesis is to be attached. Thus, the combination of Kennedy and Gibbs fails to disclose all of the elements and limitations of independent claims 1, 9, 18 and 22. For at least this reason, Kennedy and Gibbs do not render the independent claims obvious. Therefore, dependent claims 6, 14 and 27 are also patentable over the combination of Kennedy and Gibbs.

IV. 35 U.S.C. § 103 Rejection of Claims 8, 16, 21 and 29 as being Unpatentable over Kennedy in view of DiGioia, et al.

Claims 8, 16, 21 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kennedy in view of Digioia, et al. Reconsideration of these claims in view of the following remarks is respectfully requested.

DiGioia et al.

DiGioia et al. disclose an apparatus having a pre-operative geometric planner and a pre-operative kinematic biomechanical simulator in communication with the preoperative geometric planner for facilitating the implantation of an artificial component in a hip joint. DiGioia et al., Abstract. A CT scan is utilized to generate data from which a surface model of a patient's skeletal structure is developed. Digioia et al, col. 6, l. 49- col. 7, l. 10. Geometric models of the artificial component to be implanted into the joint are created/generated in any manner as is known in the art including those techniques described for creating joint models. The geometric models of the artificial components can be used in conjunction with the joint model to determine an initial static estimate of the proper size of the artificial component to be implanted

and to perform biomechanical simulations of the movement of the joint containing the implanted artificial components. DiGioia et al., Col. 7, ll. 11-23. Nowhere does the disclosure of the DiGioia et al. patent indicate that the acetabular or socket joint prosthesis is manufactured utilizing the three dimensional data for forming the attachment part. In fact, DiGioia et al. indicate that the geometric model of the acetabular cup is created either manually or in an automated fashion using conventional computer assisted design modeling techniques with implant design or manufacturing data, implying that substantially generic acetabular prosthesis will be modeled for use in performing biomechanical simulations and for implantation into the patient. DiGioia et al. indicate that the size of the acetabular cup (the functional part of the prosthesis) can be determined by the pelvis model or skeletal data but mention nothing about configuring the attachment part of the prosthesis. DiGioia et al. do indicate, however, that femoral implant can be customized to fit the femur using the femoral implant model. See DiGioia Col. 10, ll. 1-18.

Discussion Re: Patentability of Claims 8, 16, 21 and 29

Claims 8, 16, 21 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kennedy in view of Digioia, et al. Claim 8 depends from independent claim 1. Claim 16 depends directly from independent claim 9. Claim 21 depends directly from independent claim 18. Claim 29 depends directly from independent claim 22.

Independent claims 1, 9, 18 and 22 recite limitations that are not present in Kennedy as discussed above. Kennedy fails to disclose a prosthesis

(either acetabular or for a socket joint) that includes a functional part or acetabular cup and an attachment part. DiGioia et al. disclose an acetabular prosthesis that includes an acetabular cup (functional part) and an attachment part. However, the attachment part of the DiGioia et al. prosthesis is not manufactured using a second set of data derived from a first set of three dimensional data regarding the bone to which the prosthesis is to be attached. Thus, the combination of Kennedy and DiGioia et al. fails to disclose all of the elements and limitations of independent claims 1, 9, 18 and 22. For at least this reason, Kennedy and DiGioia et al. do not render the independent claims obvious. Therefore, dependent claims 8, 16, 21 and 29 are also patentable over the combination of Kennedy and Gibbs.

V. Patentability of New Claims 30 and 31.

New claim 31 depends from new claim 30. New claim 30 includes all of the elements and limitations of claim 1 as originally filed plus the additional limitation that the acetabular cup and attachment part be parts of an integral component. This additional limitation distinguishes claim 30 from Kennedy because the attachment component in Kennedy is a part of separate femoral prosthesis and not an integral part of the acetabular prosthesis. Claim 31 further narrows this additional limitation to require that the integral component be monolithic. The cited references, either alone or in combination, fail to disclose an acetabular prosthesis with an integrally formed acetabular cup and attachment part extending therefrom which is formed based on a second set of data based on

a first set of data defining in three dimensions at least a portion of a bone of a patient. Thus, claims 30 and 31 are believed to be patentable over the prior art.

VI. Conclusion

For any or all of the foregoing reasons, it is respectfully submitted that the rejections of claims 1-29 as being unpatentable over Kennedy, alone or in combination with Gibbs or DiGioia et al., have been successfully traversed, and the Applicant respectfully submits that the rejections of claims 1-29 should be withdrawn. Claims 1-31 are believed to be in condition for allowance.

Applicant respectfully requests favorable consideration of the application.

This response is being filed within the initial three-month deadline for response, to and including February 18, 2005, so no extension of time is believed to be needed. However, the Commissioner is authorized to grant any extension that may be required and to deduct any associated fees from Deposit Account 13-0014.

A prompt and favorable action on the merits is requested.

Respectfully Submitted,



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